

EXHIBIT 35

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA)
PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA)
PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS)
AMERICA, INC., and ETHYPHARM, S.A.) Civil Action No.
Plaintiff,) 3:11-CV-02506-JAP-DEA
vs.)
MYLAN PHARMACEUTICALS INC.,)
Defendant.)

DEPOSITION OF DR. STEPHEN R. BYRN

TRANSCRIPT of the stenographic notes of the
proceedings in the above-entitled matter, as taken
by and before TAB PREWETT, a Registered Professional
Reporter, a Certified LiveNote Reporter, and Notary
Public, held at the Offices of HOGAN LOVELLS US LLP,
875 Third Avenue, New York, New York 10022, on
Friday, June 8, 2012, commencing at 10 a.m.

| Page 74 | Page 76 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1 context to understand it. But, I mean, I would 2 want to look at how it's prepared and what was 3 done. 4 Q. So first ingredient -- so first 5 component, second component, under your 6 definition, could be the exact same ingredient? 7 I just want to understand your 8 position. 9 Yes or no? 10 MS. CHOW: Objection to the form. 11 A. I wouldn't -- 12 Q. That's your position? 13 A. I wouldn't rule that out, no. 14 Q. You wouldn't rule what out? 15 A. That there -- I wouldn't rule out 16 that they -- I wouldn't say that they could not 17 be. They can be the exact same ingredient, but 18 they may be processed -- I just have to look at 19 the context. 20 Q. Okay. Well, let's start with claim 21 one. 22 A. Correct.</p> | <p>1 column nine, line 27. It says: 2 "The aqueous enteric coating 3 polymer agent is preferably a methacrylate 4 copolymer. The sustained release agent is 5 preferably a methacrylate copolymer." 6 Q. So my -- the answer to my question 7 is "yes," that's your position? 8 A. Right, I think it's consistent with 9 the patent, also. 10 Q. So then let me ask you this: 11 How do you reconcile your position 12 with the -- in column nine, where it says: 13 "The sustained release agent is 14 used in an amount of 5 to 30 weight percent, 15 preferably 5 to 15 weight percent" -- and then 16 it goes on. 17 MS. CHOW: What is your question? 18 Q. How do you reconcile the fact that 19 you can use the same ingredient at the same time 20 this patent here, column nine, is suggesting 21 that one has to be in an amount relative to the 22 other?</p> |
| Page 75 | Page 77 |
| <p>1 Q. Two different ingredients, correct, 2 first component, second component? 3 MS. CHOW: Objection to the form. 4 A. I don't read it that way. 5 Q. Are there any examples in that 6 patent, in the file history, with the same 7 ingredients mixed together to achieve a 8 so-called cushioning effect to prevent cracking? 9 MS. CHOW: Objection to the form. 10 A. Although there are no examples, 11 examples aren't limited -- are not limiting. 12 Q. In other words non-limiting? 13 A. Non-limiting. I use the word -- I 14 would rather use the word "not limiting." 15 Q. So let me just back up. 16 So you are saying that the 17 sustained release agent and the enteric coating 18 agent can be the exact same ingredient? 19 MS. CHOW: Objection to the form. 20 A. Well, I am just reading the patent 21 where it says "methacrylate copolymers"; and it 22 says -- it says the "aqueous enteric" -- I am on</p> | <p>1 It seems a little inconsistent. 2 A. You know, you just have to look at 3 the context of it. 4 Q. Is it inconsistent, though; would 5 you agree? 6 A. I don't think it's inconsistent. 7 To go further, I need to look at the context. 8 Q. So everything about this whole 9 process is context. Right? You have to have 10 everything in context, it seems like. 11 MS. CHOW: Objection to the form. 12 A. I think that's -- I think generally 13 that's correct. Now, there may be some 14 instances; but, generally, in the formulation 15 field, it's pretty context-based. 16 Q. Okay. But just to back up, though, 17 there are no examples in the intrinsic evidence 18 in the specification at all showing the use of 19 the two -- the two same ingredients to form the 20 enteric coating layer? 21 MS. CHOW: Objection to the form. 22 Asked and answered.</p> |

| Page 126 | Page 128 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1 have different meanings?</p> <p>2 A. I am not sure that that is correct.</p> <p>3 Q. Okay.</p> <p>4 A. I mean, I'm not sure -- maybe I'm</p> <p>5 not sure what you are asking me. But I'm not</p> <p>6 sure. I wouldn't parse it down that way. Maybe</p> <p>7 that's a better way to say it.</p> <p>8 Q. You wouldn't parse it down which</p> <p>9 way, that they would have different meanings?</p> <p>10 A. You seem to be saying that, if</p> <p>11 something is an enteric coating agent, it can't</p> <p>12 be anything else, and vice versa. And there are</p> <p>13 lots of excipients that have multiple functions.</p> <p>14 So I'm not sure you can say that. You have to</p> <p>15 look at the system.</p> <p>16 Q. Okay. So I am asking you, though,</p> <p>17 as the person who is sitting here today defining</p> <p>18 the claim, who put a declaration in --</p> <p>19 A. Right.</p> <p>20 Q. -- enteric coating agent and</p> <p>21 sustained release agent have different meanings,</p> <p>22 correct?</p> | <p>1 Are you giving them the same</p> <p>2 meaning, right? You are defining them --</p> <p>3 A. I don't think I am. The</p> <p>4 complicated thing is I don't think I am giving</p> <p>5 them the same meaning.</p> <p>6 Q. You call them both methacrylate</p> <p>7 copolymers, right?</p> <p>8 A. Right.</p> <p>9 Q. That's how you define them in your</p> <p>10 declaration?</p> <p>11 A. Right.</p> <p>12 Q. That's the same words?</p> <p>13 A. No, because there are hundreds of</p> <p>14 methacrylate copolymers, or at least 20 of them.</p> <p>15 Q. Your position is a sustained</p> <p>16 release agent is, defined by you, a methacrylate</p> <p>17 copolymer, right?</p> <p>18 A. Right. Well, it's not defined by</p> <p>19 me. It's in the patent.</p> <p>20 Q. Okay. And it's also in your view</p> <p>21 that the enteric coating agent is also defined</p> <p>22 in the patent as a methacrylate copolymer?</p> |
| Page 127 | Page 129 |
| <p>1 I need an answer to that question.</p> <p>2 You haven't given me an answer to that question.</p> <p>3 MS. CHOW: Objection to the form.</p> <p>4 Asked and answered.</p> <p>5 A. Okay. So a sustained release</p> <p>6 agent, in my declaration, can be a methacrylate</p> <p>7 copolymer.</p> <p>8 Q. That's the same definition as you</p> <p>9 give an enteric coating agent. So then is it</p> <p>10 your testimony that they have the same meaning?</p> <p>11 If that's your position, that's</p> <p>12 fine, I will move on.</p> <p>13 MS. CHOW: Objection to the form.</p> <p>14 Asked and answered.</p> <p>15 A. Another thing I say is numerous</p> <p>16 references define enteric coating agents and</p> <p>17 sustained release agents as a methacrylate</p> <p>18 copolymer.</p> <p>19 Q. So you are giving the two claim</p> <p>20 limitations the same meaning. I don't</p> <p>21 understand what is so complicated about the</p> <p>22 question.</p> | <p>1 A. Correct.</p> <p>2 Q. And that's how you define it as</p> <p>3 well?</p> <p>4 A. Well, an enteric coating agent has</p> <p>5 to also have acid resistance. It has to be a</p> <p>6 methacrylate copolymer that has acid resistance.</p> <p>7 Q. But the sustained release agent</p> <p>8 doesn't have to?</p> <p>9 A. Correct.</p> <p>10 Q. Okay. Let me just place in front</p> <p>11 of you what is marked as Defendant's Exhibit 22</p> <p>12 and 23, product specifications for Eudragit</p> <p>13 100-55 and L 30 D-55. I'm sorry -- Eudragit --</p> <p>14 MS. CHO: One's L 30 D-55, another</p> <p>15 one is L 100-55.</p> <p>16 (Exhibit No. D 22, Product</p> <p>17 Specifications for Eudragit, is marked by the</p> <p>18 reporter for identification.)</p> <p>19 (Exhibit No. D 23, Product</p> <p>20 Specifications for Eudragit, is marked by the</p> <p>21 reporter for identification.)</p> <p>22 Q. Can you just confirm that the</p> |

| Page 166 | Page 168 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1 it, the wild, wild west?</p> <p>2 A. Correct.</p> <p>3 MS. CHOW: Objection to the form.</p> <p>4 A. I don't think it's indefinite, but</p> <p>5 I think it's quite a bit larger. I think I am</p> <p>6 being very fair to put a 10 percent number on</p> <p>7 it.</p> <p>8 Q. Well, are you being subjective, or</p> <p>9 are you being objective about it?</p> <p>10 A. I think I am being objective, but I</p> <p>11 think I am being fair. And I think I am being</p> <p>12 fair.</p> <p>13 One of the reasons I don't think</p> <p>14 it's indefinite is because the FDA required</p> <p>15 particle size specifications. And there were</p> <p>16 lots of particle size specifications being set</p> <p>17 in that time frame, and people were passing</p> <p>18 specifications. And so there was a way to get</p> <p>19 reasonable measurements of particle size in that</p> <p>20 time frame. But the errors were as I described</p> <p>21 them.</p> <p>22 Q. These two distinct concepts, the</p> | <p>1 document here.</p> <p>2 MS. CHOW: It's 21.</p> <p>3 Q. Now, going through this document,</p> <p>4 if you look at the page which I know you are</p> <p>5 quite familiar with, so let's just go right into</p> <p>6 it.</p> <p>7 The section of conversion, of</p> <p>8 scattering patterns into particle size</p> <p>9 distribution, do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And it sets out -- it says:</p> <p>12 "The algorithms used are specific</p> <p>13 to each make and model of equipment and are</p> <p>14 proprietary. Differences in the algorithms</p> <p>15 between different instruments can give rise to</p> <p>16 differences in the particle size statistics."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And do you agree with that</p> <p>20 statement?</p> <p>21 A. Yes.</p> <p>22 Q. And then it goes on to say, when</p> |
| Page 167 | Page 169 |
| <p>1 precision of the instrument itself and also the</p> <p>2 precision of the measurement, okay, if I</p> <p>3 understand it --</p> <p>4 A. Well, there is actually three</p> <p>5 different precisions of the measurement.</p> <p>6 Q. Three. So let's go over them.</p> <p>7 The precision of the instrument,</p> <p>8 the precision of the measurement of the</p> <p>9 sample --</p> <p>10 A. And there are three levels of that</p> <p>11 as described by Snorek. One of them is</p> <p>12 repeatability, precision repeatability; one of</p> <p>13 them is intermediate precision; and one of them</p> <p>14 is reproducibility.</p> <p>15 Q. So then just -- maybe I am</p> <p>16 confused. What is the third one?</p> <p>17 A. The instrument precision. So there</p> <p>18 are four total precisions that we can talk</p> <p>19 about.</p> <p>20 Q. Now, you --</p> <p>21 MR. PARKER: I don't know what I</p> <p>22 marked this as I didn't write it down, this</p> | <p>1 you are reporting particle size distribution --</p> <p>2 and it goes on, you want to be able to report</p> <p>3 the cell type, sample state, and preparation,</p> <p>4 together with the make and model of the</p> <p>5 equipment. Right?</p> <p>6 A. Now, I am just -- I am not seeing</p> <p>7 all of that. I am seeing part of that.</p> <p>8 Q. At the bottom of the page where it</p> <p>9 begins.</p> <p>10 A. Okay, I see it. Correct.</p> <p>11 Q. Now, why would you have to report</p> <p>12 the make and model of the equipment?</p> <p>13 A. Because of the previous statement.</p> <p>14 Q. Are we dealing with the instrument</p> <p>15 precision?</p> <p>16 A. The algorithms used are specific</p> <p>17 for each make and model of equipment.</p> <p>18 Q. Now, are you on the editorial board</p> <p>19 of any peer-reviewed journals?</p> <p>20 A. Yes.</p> <p>21 Q. If someone was submitting data</p> <p>22 using the Helos Rodos, what would you expect</p> |

| Page 178 | Page 180 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1 would not know how they got that number. 2 MS. CHOW: Objection to the form. 3 Q. When -- I mean "number," I am 4 talking about the patent. 5 MS. CHOW: Objection to the form. 6 A. No, I mean, a person skilled in the 7 art reading a patent would assume, like they 8 would reading a paper from J Pharm Sci, that the 9 measurement was made on the Helos Rodos as 10 described, and -- or -- and they got these 11 numbers. And then they would do the same 12 analysis I am doing and say they are plus or 13 minus 10 percent. And that's conservative. 14 I'm doing the same analysis I think 15 a person skilled in the art would do. 16 Q. Based -- okay. And you have a -- 17 the documents that you rely on to support your 18 analysis, you will agree, were published after 19 the filing date? 20 A. But the documents I am using -- 21 that's correct. But my analysis is based on my 22 experience at the time. And I think, again,</p> | <p>1 that is because they would immediately realize 2 that that is simply instrument precision. That 3 doesn't provide the information on the errors 4 that really happen that the patent is 5 addressing. 6 Q. Okay. And, again, the patent just 7 gives you the number. They don't tell you or 8 explain how that number came up, how they came 9 up with that number? 10 MS. CHOW: Objection to the form. 11 A. Well, they give us the Helos Rodos, 12 the information on that instrument. And there 13 are other methods of measurement. And from -- a 14 person skilled in the art can figure out from 15 how they are told to do the -- from the Helos 16 Rodos, how to carry out the measurements. 17 So it's not indefinite for the 18 patent -- skilled -- person skilled in the art 19 to figure out how to make the measurements or 20 what they mean. 21 Q. And one skilled in the art, well -- 22 Okay. Now, just staying on the USP</p> |
| Page 179 | Page 181 |
| <p>1 just to keep repeating, it's conservative. The 2 numbers I put in here are conservative. 3 Q. One of ordinary skill in the art 4 obviously can't go to the Snorek argument or the 5 USP in '99 because they didn't exist, and that's 6 just pretty simple, right? 7 MS. CHOW: Objection to the form. 8 Q. They didn't exist. They were 9 nonexistent. So how could they go to it? 10 A. Although they couldn't go to them, 11 they would come out with the same analysis -- 12 this is my opinion -- or even worse. But -- or 13 above 10 percent. But my opinion is that 14 10 percent is a conservative number based on all 15 of my analysis. I think that's what a person 16 skilled in the art would come up with. 17 Q. And a person of ordinary skill in 18 the art would, in your view, disregard any 19 direct information about the specific device 20 itself, the Helos Rodos? 21 MS. CHOW: Objection to the form. 22 A. The reason they would disregard</p> | <p>1 just for a minute, there's no page, but it's 2 Bates No. 226, right-hand corner, Exhibit 25. 3 A. 25. 4 Q. I'm sorry. Exhibit 25, the Bates 5 No. is 226. 6 MS. CHOW: You have got the wrong 7 one. 24, Exhibit 24. USP, right? 8 MR. PARKER: No, no. This one. 9 MS. CHOW: 29. 10 THE WITNESS: The one I have is 29. 11 I am not seeing any Bates numbers on it. 12 MR. PARKER: Well, maybe my copy is 13 different. 14 MS. CHOW: Which page of -- 15 THE WITNESS: There are pages of 16 it -- 17 MR. PARKER: It's the next-to-last 18 page. It deals with accuracy and repeatability. 19 MS. CHOW: Okay. 20 Q. I just -- where it says, "The 21 response of a laser diffraction instrument is 22 considered adequate," and it goes on, do you see</p> |

| Page 182 | Page 184 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1 that? Then it has a value of 3 percent.</p> <p>2 Can you just explain what that --</p> <p>3 that is referring to, and how to distinguish</p> <p>4 over what they are talking about it replicates,</p> <p>5 if you can?</p> <p>6 A. So this is using a certified</p> <p>7 reference standard. So you buy this material</p> <p>8 from the USP, and we had to -- actually, the</p> <p>9 NIST probably has the best one. We have had a</p> <p>10 lot of discussion of where the best reference</p> <p>11 material comes from. And these are all spheres,</p> <p>12 glass spheres of this, exactly the same particle</p> <p>13 size.</p> <p>14 So you stick -- you put those in</p> <p>15 there, and they're supposed to come out within</p> <p>16 plus or minus 3 percent. But those are, you</p> <p>17 know, not real samples. Those are standards.</p> <p>18 Those are somewhere between the Helos Rodos and</p> <p>19 the first level that Snorek uses.</p> <p>20 Q. And would that --</p> <p>21 A. Or the first level they are talking</p> <p>22 about here, because they are not real samples.</p> | <p>1 get those on a microscope. You can't get enough</p> <p>2 statistics to get a good number.</p> <p>3 And sieving has a problem with the</p> <p>4 different particle shapes. It also has a</p> <p>5 problem with charging. If you have particles</p> <p>6 that are charged, then they get electrostatic,</p> <p>7 and it doesn't give you good numbers.</p> <p>8 What was the third method?</p> <p>9 Q. Sedimentation.</p> <p>10 A. Yes, I don't know that that is</p> <p>11 widely used in the industry except for very</p> <p>12 small particles.</p> <p>13 The USP had a conference on all of</p> <p>14 these methods in 1994, and I spoke at it. And</p> <p>15 it dealt with all of this.</p> <p>16 Q. Is that information published?</p> <p>17 A. Yes.</p> <p>18 Q. Now, just staying with the '994</p> <p>19 patent for a second. If you look at column 1,</p> <p>20 there is a reference to a patent JPA -- a</p> <p>21 Japanese patent, column 1, lines 30 to 38.</p> <p>22 Do you recall or did you review</p> |
| Page 183 | Page 185 |
| <p>1 Q. Would they be used for calibrating</p> <p>2 the machine?</p> <p>3 A. Yes, they are --</p> <p>4 Q. For calibration purposes?</p> <p>5 A. Well, they are -- here they are</p> <p>6 using them for validation, but you would use</p> <p>7 similar things for calibration.</p> <p>8 Q. Of the ways of measuring particle</p> <p>9 size -- optical microscopy, sieving,</p> <p>10 sedimentation, laser diffraction -- which has</p> <p>11 the greatest variation?</p> <p>12 MS. CHOW: Objection to the form.</p> <p>13 Q. At least as of 1999, what was</p> <p>14 known.</p> <p>15 A. I don't know that I could give an</p> <p>16 exact number which is the greatest, but, in my</p> <p>17 opinion, they are all higher than laser</p> <p>18 diffraction.</p> <p>19 Optical microscopy suffers from the</p> <p>20 problem that you don't have good statistics.</p> <p>21 You probably need to analyze 100,000 particles</p> <p>22 or some large number of particles, and you can't</p> | <p>1 that piece of prior art?</p> <p>2 A. No. I don't recall reviewing it.</p> <p>3 I don't think I did. I think it's probably in</p> <p>4 Japanese.</p> <p>5 Q. And then also in the EP publication</p> <p>6 down below, two paragraphs down where it talks</p> <p>7 about particle size 100 to 100 micrometers, it's</p> <p>8 on lines 44 to 53.</p> <p>9 A. Correct.</p> <p>10 Q. Okay. Now, in the background,</p> <p>11 would you agree that here the -- the inventors</p> <p>12 are basically calling out and distinguishing the</p> <p>13 claimed invention based upon the particle size?</p> <p>14 MS. CHOW: Objection to the form.</p> <p>15 Q. Particle distribution.</p> <p>16 A. Well, I think they are</p> <p>17 distinguishing a number of other things, also.</p> <p>18 But they are mentioning particle size in their</p> <p>19 discussion.</p> <p>20 Q. And obviously these references --</p> <p>21 well, let me back up. In describing these</p> <p>22 references, they are indicating that there --</p> |

| Page 250 | Page 252 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1 Q. And given the difficulties in 2 manufacturing as you have outlined them in your 3 declaration -- so it's your position that 4 someone with a bachelor's degree and four years 5 of experience in formulation could essentially 6 solve the same problems that the inventors of 7 the '994 patent could have solved? 8 MS. CHOW: Objection to the form. 9 A. That's my opinion. I mean, the 10 four years of formulation experience would be 11 the equivalent of a Ph.D. 12 Q. Right. 13 A. So it's quite a bit of experience. 14 Q. So you guys are not -- I'm being a 15 little lax here -- it's not too far off in your 16 definitions? 17 A. Correct. 18 Q. Then on page 13 of your report, 19 that -- on paragraph 42, just staying with "the 20 person of ordinary skill in the art," then the 21 individuals -- you described that person would 22 have been able, as Dr. Shimizu has done -- was</p> | <p>1 from the beginning. I am not trying to get into 2 an obviousness analysis. I am trying to not 3 confuse you, throw you off. 4 Basically, Dr. Shimizu discusses in 5 his patent the difficulties in preparing, 6 tableting fine granules. And one of the 7 problems he was faced with -- my interpretation, 8 you can agree or not agree -- is that there are 9 issues of, when you are tableting, that, during 10 compression, they crack -- the coatings crack; 11 the enteric coatings crack, will crack. 12 Am I accurately yet briefly 13 characterizing his -- 14 A. That's one of the problems. I 15 mean, I outlined the difficulties earlier, but 16 that's one of the problems. 17 Q. That's right. You did. 18 In fact, Dr. Shimizu revolved that 19 problem, recognizing that if you add -- however 20 you called it -- add a mixture of enteric 21 coating agent or sustained release agent, that 22 you will avoid those problems?</p> |
| Page 251 | Page 253 |
| <p>1 basically he recognized that the mixing of 2 sustained release agents with the enteric 3 coating agent prevented damage to the enteric 4 coat? 5 MS. CHOW: Objection to the form. 6 A. Well, they would need his 7 declaration. They would be able to analyze his 8 data and figure that out. 9 Q. What if a person of ordinary skill 10 was faced with a problem of trying to find ways 11 to avoid damaging -- tablets getting damaged at 12 the compression? They would be able to 13 recognize what Dr. Shimizu did, essentially, was 14 basically the incorporation of sustained release 15 agent and enteric coating agents together? 16 MS. CHOW: Objection to the form. 17 A. No, I'm not sure of that. I think 18 that's part of the invention. I don't think 19 that would be apparent to somebody to do that to 20 minimize shock damage or compression damage. 21 Q. Okay. I see the confusion. Okay. 22 Try -- do this. Okay. So let me just start</p> | <p>1 MS. CHOW: Objection to the form. 2 A. I will just go with the claims. 3 The combination of coatings, two compositions, 4 like are said in the claims, avoid the problems. 5 So the claims say they don't require an 6 admixture. They just say -- well, I should -- 7 that's -- I just want to get this right -- 8 "coated by a first component which is an enteric 9 coating agent and a second component which is a 10 sustained release agent." 11 Q. Right. 12 A. Then in the patent, as we were 13 discussing this morning, it allows both of those 14 to be methacrylate polymer. 15 Q. Right. 16 A. So I am just going with that. 17 Q. That's right. And then in all of 18 the -- in the examples, the way he -- in the 19 examples that he has laid out in the 20 specification -- we went over this before -- is 21 that he essentially was able to combine the two 22 ingredients together which, in his view,</p> |

| Page 254 | Page 256 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1 resolves the problems that you talked about</p> <p>2 earlier with respect to formulating an ODT?</p> <p>3 MS. CHOW: Objection.</p> <p>4 Q. Right?</p> <p>5 MS. CHOW: Objection to the form.</p> <p>6 A. Well, in the examples he used one</p> <p>7 method of doing the claim. But that doesn't</p> <p>8 mean that there aren't other methods, and the</p> <p>9 examples are not limiting.</p> <p>10 Q. Okay. But a person of ordinary</p> <p>11 skill in the art, would they have -- so,</p> <p>12 basically, someone with a bachelor's degree and</p> <p>13 four years of experience would be able to simply</p> <p>14 resolve all of the technical difficulties in the</p> <p>15 ODT formulating field as you describe them?</p> <p>16 MS. CHOW: Objection to the form.</p> <p>17 A. I think so. I mean, that's what I</p> <p>18 am saying. I think Dr. Shimizu himself didn't</p> <p>19 have a Ph.D., or Mr. Shimizu didn't have a Ph.D.</p> <p>20 Q. Okay. Do you know whether he had a</p> <p>21 Ph.D. or not?</p> <p>22 A. I don't think he did, but now maybe</p> | <p>1 first component which is an enteric coating</p> <p>2 agent and a second component which is a</p> <p>3 sustained release agent. So I'll just go with</p> <p>4 that.</p> <p>5 Q. What do you mean? I don't know</p> <p>6 what you mean by that.</p> <p>7 A. Well, I am just -- I wasn't asked</p> <p>8 really to get into a detailed claim</p> <p>9 interpretation. But just reading them on the</p> <p>10 face, they say you have to have a first</p> <p>11 component, which is an enteric coating agent,</p> <p>12 and a second component, which is a sustained</p> <p>13 release agent.</p> <p>14 Q. Okay. So the claim -- let me back</p> <p>15 up.</p> <p>16 A. Here I am saying the enteric coated</p> <p>17 agent could be plural.</p> <p>18 Q. Okay. Aren't you saying the</p> <p>19 enteric coating layer may be constructed by</p> <p>20 plural layers? That's what you are saying</p> <p>21 there, right?</p> <p>22 A. Right. But I am not requiring --</p> |
| Page 255 | Page 257 |
| <p>1 I am wrong.</p> <p>2 Q. I don't know.</p> <p>3 THE WITNESS: What exhibit is</p> <p>4 Shimizu? Is this his?</p> <p>5 MS. CHOW: I think it's 17.</p> <p>6 (There was a discussion off the</p> <p>7 record.)</p> <p>8 A. Yes, he graduated with a bachelor's</p> <p>9 degree and then worked at Takeda, starting in</p> <p>10 1988, in Takeda's Osaka office.</p> <p>11 Q. Now, on paragraph 44 of your</p> <p>12 declaration you have "enteric coating layer."</p> <p>13 Do you see that?</p> <p>14 And you have it defined as</p> <p>15 "constructed by its" -- plural -- "layers"?</p> <p>16 A. Correct.</p> <p>17 Q. But that doesn't take away the fact</p> <p>18 that the claims still require sustained release</p> <p>19 agent as part of the enteric coating layer,</p> <p>20 right?</p> <p>21 MS. CHOW: Objection to the form.</p> <p>22 A. Well, I mean, the claims say a</p> | <p>1 maybe another way I could phrase it is -- back</p> <p>2 to what we were talking about -- the examples</p> <p>3 blended enteric coating agents, sustained</p> <p>4 release agent. But I am not requiring that. I</p> <p>5 don't remember them to be blended because of the</p> <p>6 way the claims are written.</p> <p>7 But, also, I want to just add that</p> <p>8 I haven't done a complete analysis of the claims</p> <p>9 either. And here it's saying that you can have</p> <p>10 two enteric coating layers.</p> <p>11 Q. And the way the claim reads is,</p> <p>12 basically, the enteric coating layer must</p> <p>13 consist of an enteric coating agent and a</p> <p>14 sustained release agent, at least according to</p> <p>15 the claim?</p> <p>16 MS. CHOW: Objection to the form.</p> <p>17 A. Well, I guess all I'd say is an</p> <p>18 enteric coating layer comprising a first</p> <p>19 component and a second component. I guess you</p> <p>20 could have another enteric coating layer that</p> <p>21 was -- didn't comprise two components, as long</p> <p>22 as you had one that comprised those two</p> |